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April 29, 2011

BY EXPRESS U.S. MAIL & E-MAIL

Donald M. Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
200 Independence Avenue, SW
Suite 314G
Washington, District of Columbia 20201
Donald.Berwick@CMS.hhs.gov

Re: United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Actavis Mid Atlantic, et al. -
Civil Action No. 08-10852-PBS, MDL No. 1456

Dear Dr. Berwick:

This firm represents defendant Sandoz Inc. ("Sandoz") in the above-referenced action, which is a *qui tam* lawsuit brought under the federal False Claims Act by Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care") regarding Medicaid drug price reporting. I write to request, on behalf of Sandoz and its co-defendants in this action, the oral deposition testimony of the Centers for Medicare and Medicaid Services ("CMS") concerning the areas of inquiry noticed in the subpoena served on CMS on April 14, 2011. A copy of the subpoena is attached hereto as Exhibit A.

In a letter dated April 21, 2011, counsel for CMS objected to the subpoena on the grounds that it did not comply with 45 C.F.R. §§ 2.1-2.6 (the "Touhy regulations"). Sandoz does not believe the subpoena implicates the Touhy regulations here, as it was directed to CMS as an entity under Federal Rule of Procedure 30(b)(6), and not to any particular CMS "employee," which is the subject of the Touhy regulations, *see* 45 C.F.R. § 2.1(a).¹ Nevertheless, to avoid a dispute on this issue, and without conceding the applicability of the Touhy regulations here, Defendants make

¹ Moreover, there is authority suggesting that the procedures set forth under analogous Touhy regulations are not mandated in connection with a subpoena for a Rule 30(b)(6) deposition. *See Orange Env't, Inc. v. County of Orange*, 145 F.R.D. 320, 324 (S.D.N.Y. 1992).

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the requests for testimony set forth below. Given the discovery schedule in this case, we respectfully request that you make a decision on our request on or before **May 6, 2011**. We are, of course, willing to work with CMS to find mutually agreeable dates for the requested deposition.

Section 2.4(a) of the Code of Federal Regulations provides that requests for testimony “must state the nature of the requested testimony, why the information sought is unavailable by any other means, and why the testimony would be in the interest of the DHHS or the federal government.” For the reasons set forth below, and for the reasons previously explained to and already in the possession of CMS and its counsel, CMS should allow the requested testimony.

1. Nature of the Requested Testimony

Defendants request the testimony of CMS regarding their drug pricing information, including without limitation Average Manufacturer Prices (AMPs), provided in connection with pharmaceutical products under Medicaid. (Exhibit A, Area of Inquiry 1.) Included in this request is testimony regarding any analysis, evaluation, review of or reliance by CMS on any representation regarding such information provided by Defendants. (*Id.*)

Defendants also request the testimony of CMS concerning CMS’s and the federal government’s policies and decisions to encourage the dispensing of generic drugs under Medicaid. (*Id.*, Area of Inquiry 2.)

Finally, Defendants request the testimony of CMS regarding CMS’s consideration, approval, or disapproval of Section 4.19(b) of proposed or actual amendments to state Medicaid plans submitted under 42 U.S.C. § 1396(a), including proposed or actual amendments that include State Maximum Allowable Cost Programs (SMAC Programs) and proposed or actual amendments that include differential Estimated Acquisition Cost (EAC) calculations between branded or single-source pharmaceutical products and generic or multi-source pharmaceutical products. (*Id.*, Area of Inquiry 3.) Included in this request is testimony regarding specific State Plan Amendments for eleven states. (*Id.*)

2. Availability through Other Means

The information that Defendants request is not available through other means.

With regard to Defendants’ request for testimony regarding their AMPs and other pricing information, CMS is uniquely positioned to provide relevant testimony. The federal government has required pharmaceutical manufacturers to provide their AMPs and relies on such information in connection with the Medicaid rebate program, and CMS has specifically approved State Plan Amendments that provide for reimbursement based on pricing information supplied by certain of the Defendants, such as AWP and WACs. CMS’s understanding of and rationale to permit the use of such information is available only through CMS. Moreover, such pricing information is specific to Defendants and has not been the subject of prior depositions of CMS officials.

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Similarly, CMS is uniquely positioned to provide testimony concerning its and the federal government's policies and decisions to encourage the dispensing of generic drugs under Medicaid. Such testimony is not available from Ven-A-Care or other third parties and is not available through other means. Moreover, any prior deposition testimony CMS officials may have given regarding generic drugs is not sufficient to address the unique issues raised in this particular litigation as they pertain to those Defendants.

Testimony concerning CMS's consideration, approval, or disapproval of proposed and actual State Plan Amendments likewise is unavailable through other means. CMS is the sole agency responsible for the approval of Medicaid State Plan Amendments, and only it can provide the information it took into account, the rationale it applied, and the decisions it made with regard to proposed State Plan Amendments. Such information is not sufficiently reflected in the State Plan documents themselves or the related written correspondence or deposition testimony produced to date. Finally, Defendants in this cases have not had any meaningful opportunity to ask CMS questions with respect to the unique issues raised in this litigation.

3. Interests of DHHS and the Federal Government

It is in the interest of DHHS and the federal government to provide the testimony requested by Defendants. Ven-A-Care is alleging violations of the federal False Claims Act for overpayments that the federal government allegedly made in connection with pharmaceutical reimbursements under the Medicaid program. The federal government is a party in interest in this case, and the requested testimony goes directly to the federal government's understanding of and decisions with regard to the reimbursement system under Medicaid, which are crucial issues in this action. It is in the interest of the federal government to permit a complete record to be established on these and other issues and that the jury have a full understanding of the relevant facts in this case.

Moreover, providing this testimony is in the interest of DHHS and the federal government because it avoids unwarranted litigation to obtain it. If the agency decides to withhold the requested information, Defendants may have no choice but to engage in motion practice before the Court in order to obtain testimony to establish meritorious defenses in this case.

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For the foregoing reasons, Defendants request that you authorize the requested testimony as soon as possible, and in any event, no later than May 24, 2011.

Sincerely,



Paul B. Carberry

Enclosure

Donald Berwick, M.D.

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cc: William B. Schultz, Esq. (by e-mail to William.Schultz@hhs.gov)
Mark D. Polston, Esq. (by e-mail to Mark.Polston@hhs.gov)
Laurie Oberembt, Esq. (by e-mail to Laurie.Oberembt@usdoj.gov)
Justin Draycott, Esq. (by e-mail to Justin.Draycott@usdoj.gov)
Counsel for Actavis, Par and Watson (by e-mail)

EXHIBIT A

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

In re Pharmaceutical Industry Average Wholesale Price Litigation
United States Of America ex rel. Ven-A-Care of the Florida Keys, Inc.

Plaintiff

v.

Actavis Mid Atlantic LLC, et al.

Defendant

08-cv-10852-PBS

MDL No. 1456

Master File No. 01-12257-PBS

Civil Action No. Subcategory No. 06-1137-PBS

(If the action is pending in another district, state where:

District of Massachusetts)

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Centers for Medicare and Medicaid Services, Attn: United States Dept. of Health and Human Services Office of the General Counsel, Room 711-E, 200 Independence Avenue, SW, Washington, DC 20201

☒ **Testimony:** **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization that is *not* a party in this case, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

Please see attached Schedule A.

Place: White & Case LLP, 701 Thirteenth Street, NW,
Washington D.C. 20005

Date and Time:

05/06/2011 10:00 am

The deposition will be recorded by this method: _____

- ☐ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material:

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date:

April 14, 2011

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail, and telephone number of the attorney representing (name of party)

Sandoz Inc.

, who issues or requests this subpoena, are:
Daniel Cohen, 1155 Avenue of the Americas, New York, NY 10036, daniel.cohen@whitecase.com, 212-819-7945.

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena for *(name of individual and title, if any)* _____
was received by me on *(date)* _____.

☐ I served the subpoena by delivering a copy to the named individual as follows: _____

_____ on *(date)* _____; or

☐ I returned the subpoena unexecuted because: _____

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also
tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of
\$ _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ 0.00.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)**(c) Protecting a Person Subject to a Subpoena.**

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

(A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

(A) When Required. On timely motion, the issuing court must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person — except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) When Permitted. To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information;

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

(iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

(C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(d) Duties in Responding to a Subpoena.

(1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:

(A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

(A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

SCHEDULE A

DEFINITIONS

1. “AMP” or “Average Manufacturer Price” shall have the meaning set forth in 42 U.S.C. § 1396r-8(k)(1).
2. “CMS” means the United States Centers for Medicare and Medicaid Services; all of its predecessors (including the Health Care Financing Administration or HCFA); constituent parts (including the Department of Health and Human Services); present and former directors, officers, employees, agents, attorneys, and accountants; and any other person who currently or formerly acted or purported to act on their behalf.
3. “Defendants” refers to Actavis MidAtlantic LLC, Alpharma USPD Inc. f/k/a Barre National Inc., and Barre Parent Corp.; Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.; Sandoz Inc. f/k/a Geneva Pharmaceuticals Inc.; and Watson Pharmaceuticals, Inc. and Schein Pharmaceutical, Inc. (n/k/a Watson Pharma, Inc.).
4. “Generic Drugs” shall mean drugs to which pharmaceutically and therapeutically equivalent drugs containing the same active ingredient exist.
5. “Including” means including without limitation.
6. “MAC” or “Maximum Allowable Cost” shall have the meaning set forth in 42 C.F.R. § 50.504 or any analogous state statute or regulation.
7. “Medicaid” means the Medicaid Program, as administered by the various states.
8. “Program” means any program under which Medicaid pays reimbursement for pharmaceuticals and includes all State Medicaid Programs and any insurance program that provides pharmaceutical benefits to State and/or federal employees.

9. “Regarding,” “relating to,” or “referring to” means constituting, containing, concerning, referring to, embodying, reflecting, analyzing, evidencing, discussing, identifying, illustrating, stating, supporting, refuting, responding to, commenting on, evaluating, about, mentioning, dealing with, or in any way pertaining to the relevant subject matter or person(s).

10. “State Medicaid Programs” means the State agencies responsible for carrying out the Medicaid Program in the fifty States and the District of Columbia; all their branches, agencies, committees, or departments; all their current and former administrators, staff, employees, agents, consultants, accountants, or attorneys; and any other person who currently or formerly acted or purported to act on their behalf.

AREAS OF INQUIRY

1. The drug pricing information (including without limitation AMPs) provided by Defendants in connection with their pharmaceutical products under Medicaid, including without limitation any analysis, evaluation, review of, or reliance on any representations regarding drug pricing provided the Defendants.

2. CMS’s and the federal government’s policies and decisions to encourage the dispensing of Generic Drugs under Medicaid.

3. CMS’s consideration, approval, or disapproval of Section 4.19(b) of all proposed or actual amendments to state Medicaid plans submitted under 42 U.S.C. § 1396(a), including without limitation proposed or actual amendments that include State Maximum Allowable Cost programs, proposed or actual amendments that include differential EAC calculations between branded or single-source products and generic or multi-source products, and the following state plan amendments:

- a. *Arkansas*: State Plan Amendment #89-24 (changing from AWP to AWP - 10.5%); State Plan Amendment #01-038 (changing to AWP - 14% for brand drugs and AWP - 25% for generic drugs); and State Plan Amendment #02-008 (changing to AWP - 20% for generic drugs). Persons with relevant knowledge of these State Plan Amendments may include Jerry D. Sconce, James R. Merryman, James L. Reed, and Calvin G. Cline.
- b. *California*: State Plan Amendment #03-012 (changing from AWP - 5% to AWP - 10%). Persons with relevant knowledge of this State Plan Amendment may include Linda Minamoto and Dennis G. Smith.
- c. *Idaho*: State Plan Amendment #99-001 (changing from AWP to AWP - 11%); and State Plan Amendment #01-012 (changing to AWP - 12%). Persons with relevant knowledge of these State Plan Amendments may include Robert Reed, Debbie Chang, Nicole Tapay, Sue Gaston, Teresa Trimble, Maria Garza, and Kimberly Howell.
- d. *Illinois*: State Plan Amendment #00-15 (changing to a lower-of formula based on AWP and WAC); and State Plan Amendment #03-09 (changing to AWP - 12% for brand drugs and AWP - 25% for generic drugs). Persons with relevant knowledge of these State Plan Amendments may include Vera Drivalas and Cheryl A. Harris.
- e. *Kentucky*: State Plan Amendment #02-04 (changing from AWP - 10% to AWP - 12%). Persons with relevant knowledge of this State Plan Amendment may include Eugene Grasser and Rhonda R. Cottrell.

- f. *Louisiana*: State Plan Amendment #01-08 (changing from AWP - 15% to AWP - 13.5% for independent pharmacies and AWP - 16.5% to AWP - 15% for chain pharmacies). Persons with relevant knowledge of this State Plan Amendment may include Joe Reeder, Larry Reed, Kim Howell, and Andrew Fredrickson.
- g. *Minnesota*: State Plan Amendment #03-001 (changing from AWP - 9% to AWP - 14%); and State Plan Amendment #03-029 (changing to AWP - 11.25%). Persons with relevant knowledge of these State Plan Amendments may include Deirdre Duzor, Doris Ross, and Cheryl Harris.
- h. *Oregon*: State Plan Amendment #01-02 (changing from AWP - 11% to AWP - 13%); State Plan Amendment #02-004 (changing to AWP - 14%); State Plan Amendment #02-016 (changing to AWP - 11% for institutional pharmacies); and State Plan Amendment #02-017 (changing to AWP - 15%). Persons with relevant knowledge of these State Plan Amendments may include Maria Garza, Teresa Trimble, Bunnee Butterfield, Larry Reed, and Karen S. O'Connor.
- i. *South Carolina*: State Plan Amendment #00-009 (changing from AWP - 13% to AWP - 10%). Persons with relevant knowledge of this State Plan Amendment may include Jessie Spillers, Larry Reed, Eugene Grasser, and Cheryl Austein Casnoff.
- j. *Washington*: State Plan Amendment #02-022 (changing from AWP - 11% to AWP - 14%). Persons with relevant knowledge of this State Plan Amendment may include Deirdre Duzor and Karen S. O'Connor.
- k. *Wisconsin*: State Plan Amendment #01-009 (changing from AWP - 10% to AWP - 11.25%); and State Plan Amendment #03-010 (changing to AWP - 12% in

August 2003 and AWP - 13% in July 2004). Persons with relevant knowledge of these State Plan Amendments may include Cheryl A. Harris and Pamela Carson.